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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,917	03/16/2004	Gertrud Hotten	2923-609	2179

6449 7590 08/10/2007

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EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
08/10/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/800,917	HOTTEN ET AL.	
	Examiner	Art Unit	
	David S. Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-15* is/are pending in the application.

4a) Of the above claim(s) *8,9,12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7,10,11,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *6-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/288,508.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0304,0704*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 6–15 are pending.

Applicant's election of group I, claims 6–7 and 10–15, drawn to methods of treatment comprising administering MP52, in the reply filed on 01/09/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 8–9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01/09/2007.

Applicant's election of the species treatment of skin in the reply filed on 05/18/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 12–13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 05/18/2007.

The species connective tissues has been rejoined for examination on the merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6–7 and 14–15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,120,760 in view of Yamashita (Exp Cell Res. 1997 Aug 25;235(1):218-26).

U. S. Patent No. 6,120,760 claims a method for the treatment of bone and cartilage defects comprising administering a composition containing a protein of the TGF-β family comprising the amino acid sequence of SEQ ID NO: 3 or the mature portion thereof and an acceptable carrier (claim 7). SEQ ID NO: 3 of U. S. Patent No. 6,120,760 is identical to amino acids 101-501 of SEQ ID NO: 2 of the present application, as indicated below:

```
  Query Match             79.8%;  Score 2133;  DB 2;  Length 401;
  Best Local Similarity   100.0%;  Pred. No. 3.7e-160;
  Matches  401;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy        101 PGGPEPKPGHPPQTRQATARTVTPKGQLPGGKAPPKAGSVPSSFLLKKAREPGPPREPKE 160
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 PGGPEPKPGHPPQTRQATARTVTPKGQLPGGKAPPKAGSVPSSFLLKKAREPGPPREPKE 60

Qy        161 PFRPPPITPHEYMLSLYRTLSDADRKGGNSSVKLEAGLANTITSFIDKGQDDRGPVVRKQ 220
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 PFRPPPITPHEYMLSLYRTLSDADRKGGNSSVKLEAGLANTITSFIDKGQDDRGPVVRKQ 120

Qy        221 RYVFDISALEKDGLLGAELRILRKKPSDTAKPAAPGGGRAAQLKLSSCPSGRQPASLLDV 280
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 RYVFDISALEKDGLLGAELRILRKKPSDTAKPAAPGGGRAAQLKLSSCPSGRQPASLLDV 180

Qy        281 RSVPGLDGSGWEVFDIWKLFRNFKNSAQLCLELEAWERGRAVDLRGLGFDRAARQVHEKA 340
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 RSVPGLDGSGWEVFDIWKLFRNFKNSAQLCLELEAWERGRAVDLRGLGFDRAARQVHEKA 240
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Qy        341 LFLVFGRTKKRDLFFNEIKARSGQDDKTVYEYLFSQRRKRRAPLATRQGKRPSKNLKARC 400
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 LFLVFGRTKKRDLFFNEIKARSGQDDKTVYEYLFSQRRKRRAPLATRQGKRPSKNLKARC 300

Qy        401 SRKALHVNFKDMGWDDWIIAPLEYEAFHCEGLCEFPLRSHLEPTNHAVIQTLMNSMDPES 460
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 SRKALHVNFKDMGWDDWIIAPLEYEAFHCEGLCEFPLRSHLEPTNHAVIQTLMNSMDPES 360

Qy        461 TPPTCCVPTRLSPISILFIDSANNVVYKQYEDMVVESCGCR 501
              |||||||||||||||||||||||||||||||||||||||||
Db        361 TPPTCCVPTRLSPISILFIDSANNVVYKQYEDMVVESCGCR 401.
```

A protein encoded by a DNA molecule which comprises a part of SEQ ID NO: 1 comprising nucleotides 1783-2142 and encodes the mature protein and a protein encoded by a DNA molecule comprising a nucleotide sequence which encodes the mature protein with amino acids 382-501 according to SEQ ID NO: 2, as recited in the instant claims, encompasses a protein of the TGF-β family comprising the amino acid sequence of SEQ ID NO: 3 or the mature portion thereof, as recited in the patent's claims. Wound healing and tissue regeneration, as recited in the instant claims, are generic to and fully encompass the treatment of bone and cartilage defects, as recited in the patent claims. The claims of U. S. Patent No. 6,120,760 are silent with respect to the induction of angiogenesis. However, inducing angiogenesis would flow naturally from following the teaches of the claims of the patent, as evidenced by Yamashita (Abstract).

Claims 6–7, 10–11 and 14–15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10–13 of copending Application No. 11/080,494 in view of Yamashita (Exp Cell Res. 1997 Aug 25;235(1):218-26).

Copending U. S. Application No. 11/080,494 claims a method of treating a disease or condition where the growth of bone and/or cartilage is desirable in a patient in need thereof (claim 10), a method of inducing at least one of bone or cartilage growth in a patient in need thereof (claim 11), a method for inducing bone growth for the treatment of a bone defect or bone

fracture where the growth of bone is desirable, for application in the jaw region or dental region or for immobilizing movable bone parts in a patient (claim 12) for the treatment of periodontitis (claim 13), the method comprising implanting an implant material suitable for cartilage, bone, or cartilage and bone growth comprising a matrix material which is composed of a crystallographically phase- pure calcium phosphate and applied in and/or on said matrix a cartilage inducing, bone inducing, or cartilage and bone inducing MP52 protein, wherein the MP52 protein is selected from the group consisting of (a) a protein comprising amino acid 1 to 501, 28 to 501, 361-400 to 501, 381 to 501, or 382 to 501 of SEQ ID NO. 1, into the patient. SEQ ID NO: 1 of copending U. S. Application No. 11/080,494 is identical to SEQ ID NO: 2 of the instant application, as indicated below:

```
  Query Match             100.0%;  Score 2673;  DB 6;  Length 501;
  Best Local Similarity   100.0%;  Pred. No. 1e-172;
  Matches  501;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MRLPKLLTFLLWYLAWLDLEFICTVLGAPDLGQRPQGTRPGLAKAEAKERPPLARNVFRP 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MRLPKLLTFLLWYLAWLDLEFICTVLGAPDLGQRPQGTRPGLAKAEAKERPPLARNVFRP 60

Qy         61 GGHSYGGGATNANARAKGGTGQTGGLTQPKKDEPKKLPPRPGGPEPKPGHPPQTRQATAR 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 GGHSYGGGATNANARAKGGTGQTGGLTQPKKDEPKKLPPRPGGPEPKPGHPPQTRQATAR 120

Qy        121 TVTPKGQLPGGKAPPKAGSVPSSFLLKKAREPGPPREPKEPFRPPPITPHEYMLSLYRTL 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 TVTPKGQLPGGKAPPKAGSVPSSFLLKKAREPGPPREPKEPFRPPPITPHEYMLSLYRTL 180

Qy        181 SDADRKGGNSSVKLEAGLANTITSFIDKGQDDRGPVVRKQRYVFDISALEKDGLLGAELR 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 SDADRKGGNSSVKLEAGLANTITSFIDKGQDDRGPVVRKQRYVFDISALEKDGLLGAELR 240

Qy        241 ILRKKPSDTAKPAAPGGGRAAQLKLSSCPSGRQPASLLDVRSVPGLDGSGWEVFDIWKLF 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 ILRKKPSDTAKPAAPGGGRAAQLKLSSCPSGRQPASLLDVRSVPGLDGSGWEVFDIWKLF 300

Qy        301 RNFKNSAQLCLELEAWERGRAVDLRGLGFDRAARQVHEKALFLVFGRTKKRDLFFNEIKA 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 RNFKNSAQLCLELEAWERGRAVDLRGLGFDRAARQVHEKALFLVFGRTKKRDLFFNEIKA 360

Qy        361 RSGQDDKTVYEYLFSQRRKRRAPLATRQGKRPSKNLKARCSRKALHVNFKDMGWDDWIIA 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 RSGQDDKTVYEYLFSQRRKRRAPLATRQGKRPSKNLKARCSRKALHVNFKDMGWDDWIIA 420

Qy        421 PLEYEAFHCEGLCEFPLRSHLEPTNHAVIQTLMNSMDPESTPPTCCVPTRLSPISILFID 480
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                    ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        421 PLEYEAFHCEGLCEFPLRSHLEPTNHAVIQTLMNSMDPESTPPTCCVPTRLSPISILFID 480

Qy        481 SANNVVYKQYEDMVVESCGCR 501
                    ||||||||||||||||||||
Db        481 SANNVVYKQYEDMVVESCGCR 501.
```

Wound healing and tissue regeneration, as recited in the instant claims, are generic to and fully encompass treating a disease or condition where the growth of bone and/or cartilage is desirable in a patient in need thereof, a method of inducing at least one of bone or cartilage growth in a patient in need thereof, a method for inducing bone growth for the treatment of a bone defect or bone fracture where the growth of bone is desirable, for application in the jaw region or dental region or for immobilizing movable bone parts in a patient and for the treatment of periodontitis, as recited in the copending application's claims. The matrix, carrier diluent and/or filler of the instant claims are generic to and fully encompass the implant material of the copending application's claims. The claims of the copending application are silent with respect to the induction of angiogenesis. However, inducing angiogenesis would flow naturally from following the teaches of the claims of the copending application, as evidenced by Yamashita (Abstract).

This is a provisional obviousness-type double patenting rejection.

Claims 7 and 14–15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 3, 8, 12 and 42–44 of copending Application No. 10/356,513 in view of Yamashita (Exp Cell Res. 1997 Aug 25;235(1):218-26).

U. S. Application No. 10/356,513 claims a method of treating injuries to the neuronal layer of the retina and the optic nerve and/or stimulating the outgrowth of nerve fibers from the

retina in a patient in need of such treatment, the method comprising administering to the patient a therapeutically effective amount of biologically active MP52 selected from the group consisting of (a) the mature part of the protein sequence shown in SEQ ID NO: l; (b) parts of the mature protein which have essentially the same survival promoting effect on dopaminergic neurons as the mature part of the protein sequence shown in SEQ ID NO: l; and (c) mature proteins with a modified N-terminus which have essentially the same survival promoting effect on dopaminergic neurons as the mature part of the protein sequence shown in SEQ ID NO: 1.

SEQ ID NO: 1 of copending U. S. Application No. 10/356,513 is identical to SEQ ID NO: 2 of the instant application, as indicated below:

```
  Query Match            100.0%;  Score 2673;  DB 4;  Length 501;
  Best Local Similarity  100.0%;  Pred. No. 1e-172;
  Matches  501;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MRLPKLLTFLLWYLAWLDLEFICTVLGAPDLGQRPQGTRPGLAKAEAKERPPLARNVFRP 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MRLPKLLTFLLWYLAWLDLEFICTVLGAPDLGQRPQGTRPGLAKAEAKERPPLARNVFRP 60

Qy         61 GGHSYGGGATNANARAKGGTGQTGGLTQPKKDEPKKLPPRPGGPEPKPGHPPQTRQATAR 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 GGHSYGGGATNANARAKGGTGQTGGLTQPKKDEPKKLPPRPGGPEPKPGHPPQTRQATAR 120

Qy        121 TVTPKGQLPGGKAPPKAGSVPSSFLLKKAREPGPPREPKEPFRPPPITPHEYMLSLYRTL 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 TVTPKGQLPGGKAPPKAGSVPSSFLLKKAREPGPPREPKEPFRPPPITPHEYMLSLYRTL 180

Qy        181 SDADRKGGNSSVKLEAGLANTITSFIDKGQDDRGPVVRKQRYVFDISALEKDGLLGAELR 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 SDADRKGGNSSVKLEAGLANTITSFIDKGQDDRGPVVRKQRYVFDISALEKDGLLGAELR 240

Qy        241 ILRKKPSDTAKPAAPGGGRAAQLKLSSCPSGRQPASLLDVRSVPGLDGSGWEVFDIWKLF 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 ILRKKPSDTAKPAAPGGGRAAQLKLSSCPSGRQPASLLDVRSVPGLDGSGWEVFDIWKLF 300

Qy        301 RNFKNSAQLCLELEAWERGRAVDLRGLGFDRAARQVHEKALFLVFGRTKKRDLFFNEIKA 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 RNFKNSAQLCLELEAWERGRAVDLRGLGFDRAARQVHEKALFLVFGRTKKRDLFFNEIKA 360

Qy        361 RSGQDDKTVYEYLFSQRRKRRAPLATRQGKRPSKNLKARCSRKALHVNFKDMGWDDWIIA 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 RSGQDDKTVYEYLFSQRRKRRAPLATRQGKRPSKNLKARCSRKALHVNFKDMGWDDWIIA 420

Qy        421 PLEYEAFHCEGLCEFPLRSHLEPTNHAVIQTLMNSMDPESTPPTCCVPTRLSPISILFID 480
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        421 PLEYEAFHCEGLCEFPLRSHLEPTNHAVIQTLMNSMDPESTPPTCCVPTRLSPISILFID 480
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```
Qy        481 SANNVVYKQYEDMVVESCGCR 501
              |||||||||||||||||||||
Db        481 SANNVVYKQYEDMVVESCGCR 501.
```

Wound healing and tissue regeneration, as recited in the instant claims, are generic to and fully encompass treating injuries to the neuronal layer of the retina and the optic nerve and/or stimulating the outgrowth of nerve fibers from the retina in a patient in need of such treatment, as recited in the claims of the copending application. The claims of the copending application are silent with respect to a matrix, carrier diluent and/or filler. However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to administer MP52, as taught by the claims of the copending application, and to modify that teaching by administering a matrix, carrier diluent and/or filler along with the MP52, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification in order to administer the MP52. The claims of the copending application are silent with respect to the induction of angiogenesis. However, inducing angiogenesis would flow naturally from following the teaches of the claims of the patent, as evidenced by Yamashita (Abstract).

This is a provisional obviousness-type double patenting rejection.

Claims 6, 7, 10, 11, 14 and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 41–50 of copending Application No. 10/472,389 in view of Yamashita (Exp Cell Res. 1997 Aug 25;235(1):218-26). The copending application claims a method for improving wound healing and/or wound repair of skin tissue in a mammal, comprising administering GDF-5 or a biosynthetic derivative or part thereof to a mammal in need of wound healing or wound repair of skin tissue (claims 41–50). The GDF-5 of the copending application's claims is generic to and fully encompasses the MP52

of the instant claims. The claims of the copending application are silent with respect to a matrix, carrier diluent and/or filler. However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to administer MP52, as taught by the claims of the copending application, and to modify that teaching by administering a matrix, carrier diluent and/or filler along with the MP52, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification in order to administer the MP52. The claims of the copending application are silent with respect to the induction of angiogenesis. However, inducing angiogenesis would flow naturally from following the teaches of the claims of the patent, as evidenced by Yamashita (Abstract).

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6, 7, 10, 11, 14 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Celeste (5,658,882) as evidenced by Yamashita (Exp Cell Res. 1997 Aug 25;235(1):218-26).

A 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to:

(A) Prove the primary reference contains an "enabled disclosure;"
(B) Explain the meaning of a term used in the primary reference; or
(C) Show that a characteristic not disclosed in the reference is inherent.

MPEP § 2131.01.

This rejection is based upon an effective filing date for Celeste of 03/25/1994 , which is obtained via U. S. Application No. 08/217,780.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Celeste discloses a method for inducing tendon/ligament-like tissue formation in a patient in need of same comprising administering to said patient an effective amount of a composition comprising a protein which exhibits the ability to induce formation of tendon/ligament-like tissue, said protein having an amino acid sequence shown in SEQ ID NO: 4 (column 3, full paragraph 3). Celeste's SEQ ID NO: 4 is identical to amino acids 382-501 of SEQ ID NO: 2. Celeste's method further comprises administering a matrix, carrier, diluent and/or filler along with said protein having an amino acid sequence shown in SEQ ID NO: 4 (paragraph bridging columns 12-13 through paragraph bridging columns 13-14).

The induction of angiogenesis is inherent to the Celeste's method, as evidenced by Yamashita (Abstract).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating, does not reasonably provide

enablement for a method of prevention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are directed to or encompass a method for preventing damage to bone, cartilage, connective tissues, skin, mucous membranes, epithelium or teeth. Preventing damage encompasses preventing traumatic injuries, such as incineration, gunshots, traumatic crush injuries, etc. The specification lacks working examples of, and guidance for, preventing damage that result from traumatic injuries. The examiner is aware working examples are not required. Lack of a working example is, however, a factor to be considered. There is no evidence of record that MP52 could prevent damage resulting from traumatic injuries. In view of the breadth of the claims, and the lack of direction and working examples provided by the inventor, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of improving wound healing of the skin and tissue regeneration of the skin, does not reasonably provide enablement for a method of improving wound healing and tissue regeneration without regard to the type of tissue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are directed to or encompass improving any and/or all types of wound healing and tissue regeneration. Therefore, the claims encompass the regeneration of tissues comprising

permanent cells that are retained throughout adult life and seem never to divide and which cannot be replaced if lost, such as almost all nerve cells. See Alberts (Molecular Biology of the Cell, 1994), page 1142, last full paragraph. Although most permanent cells renew their parts (See Alberts, pages 1144-1145), the claims encompass the regeneration of permanent cells, which cannot be replaced if lost. The specification lacks working examples of, and guidance for, the regeneration of permanent cells, which cannot be replaced if lost. In view of the breadth of the claims, and the lack of direction and working examples provided by the inventor, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 9:00 A.M. TO 5:30 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISORS, JANET ANDRES OR GARY NICKOL, CAN BE REACHED ON (571)272-0867 OR (571)272-0835, RESPECTIVELY.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE HTTP://PAIR-DIRECT.USPTO.GOV. CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE) FOR QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM,

/DAVID ROMEO/
PRIMARY EXAMINER
ART UNIT 1647

DSR
AUGUST 5, 2007